

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No.: 5,254,556

Issued: October 19, 1993

Expiration Date: October 27, 2012

Inventors: Cornelus G. M. Janssen, Alfonsus G. Knaeps, Ludo E. J. Kennis, Jan Vandenberg

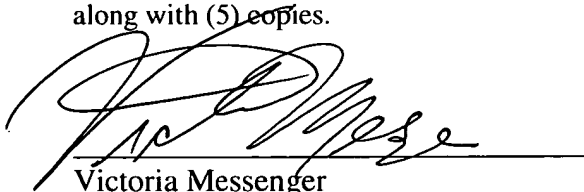
Title: 3-PIPERIDINYL-1,2-BENZISOXAZOLES

Mail Stop Hatch-Waxman PTE  
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**PATENT EXTENSION**  
**OPLA**

**TRANSMITTAL OF APPLICATION FOR EXTENSION OF PATENT TERM (37 C.F.R.  
§ 1.740) and Application for Interim Patent Term Extension Under 37 CFR 1.760**

Attached hereto is an Application for Extension of Patent Term for the above-identified Patent along with (5) copies.



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**APPLICATION FOR INTERIM EXTENSION OF PATENT TERM (37 C.F.R. § 1.760)**

**Dear Sir:**

Applicant hereby requests a fourth Interim Patent Term Extension for a period of eleven months and approximately 19 days as is provided under 35 U.S.C 156(e)(2) and 37 CFR 1.760 from October 27, 2012 until the expiration of the extended patent term on or about October 15, 2013 to allow for additional time for reviewing and granting applicants' previously filed Application for Patent Term Extension.

**BACKGROUND**

An initial application for Interim Extension of Patent Term pursuant to 37 CFR 1.790 was filed on July 7, 2009 for US Patent 5,254,556 ('556 Patent). The '556 Patent claims the active ingredient of the INVEGA SUSTENNA™ Extended-Release Injectable Suspension, paliperidone palmitate, which has undergone regulatory review. The '556 Patent includes 6 claims, of which Claims 1 and 2 claim the Product, and Claim 3 claims the use of the Product.

The FDA on July 31, 2009 granted a marketing authorization for the INVEGA SUSTENNA™ (Paliperidone Palmitate) Extended-Release Injectable Suspension, which was under regulatory review under the Federal Food Drug & Cosmetic Act ("FDC Act") §505(b), 21 U.S.C. §355 (new drugs).

An Application for Patent Term Extension in compliance with 37 CFR 1.740 and an Application for Interim Extension of Patent Term under 37 CFR 1.760 were filed August 6, 2009.

The first request for Interim Patent Extension of the Patent Term was granted on or about October 7, 2009 by the very honorable Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, David J. Kappos. The first Interim Patent Extension extended the term of the '556 patent from October 27, 2009 until October 27, 2010.

The second request for Interim Patent Extension of the Patent Term was granted on or about October 1, 2010 by the very honorable Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, David J. Kappos. The second Interim Patent Extension extended the term of the '556 patent from October 27, 2010 until October 27, 2011.

The third request for Interim Patent Extension of the Patent Term was granted on or about September 30, 2011 by the very honorable Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, David J. Kappos. The third Interim Patent Extension extended the term of the '556 patent from October 27, 2011 until October 27, 2012.

The above-identified patent expires on October 27, 2012, more than three months from the date of this application.

#### **FEE STATUS**

Authorization is hereby made to charge the amount of \$220.00 to Deposit Account No. 10-0750/JAB0828/HBW.

Charge any additional fees required by this paper or credit any overpayment in the manner authorized above.

Four additional copies of this application are attached, making a total of five copies being submitted (See§ MPEP 2753 (8<sup>th</sup> Edition).

Date: July 24, 2012

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